

Representative Raymond P. Ward proposes the following substitute bill:

PHARMACY AMENDMENTS

2024 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Raymond P. Ward

Senate Sponsor: Evan J. Vickers

LONG TITLE

General Description:

This bill allows pharmacists and pharmacy interns to substitute prescribed drugs under certain circumstances.

Highlighted Provisions:

This bill:

- ▶ defines terms;
- ▶ allows pharmacists and pharmacy interns to substitute prescribed drugs under certain circumstances;
- ▶ requires the Division of Professional Licensing, in consultation with certain licensing boards, to develop a therapeutically equivalent drug list and a therapeutically similar drug list; and
- ▶ provides rulemaking authority.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:



26 [58-17b-605](#), as last amended by Laws of Utah 2020, Chapter 372

27

28 *Be it enacted by the Legislature of the state of Utah:*

29 Section 1. Section **58-17b-605** is amended to read:

30 **58-17b-605. Therapeutically equivalent and similar drug products.**

31 (1) For the purposes of this section:

32 (a) (i) "Drug" is as defined in Section [58-17b-102](#).

33 (ii) "Drug" [~~does not mean a "biological product"~~] includes a biological product as
34 defined in Section [58-17b-605.5](#).

35 (b) "~~Drug product equivalent~~ Therapeutically equivalent drug product" means[:]
36 [(~~+~~) a drug product that:

37 (i) is designated as the therapeutic equivalent of another drug product in the Approved
38 Drug Products with Therapeutic Equivalence Evaluations prepared by the Center for Drug
39 Evaluation and Research of the United States Food and Drug Administration[~~;~~ and]; or

40 (ii) [~~notwithstanding Subsection (1)(b)(i), an appropriate substitute for albuterol~~
41 ~~designated by division rule made under Subsection (9)]~~

42 (A) has the same active ingredient of another drug product; and

43 (B) is on the list of therapeutically equivalent drug products created by the division in
44 accordance with Subsection (9).

45 (c) "Osteopathic Physician and Surgeon's Licensing Board" means the board created in
46 Section [58-68-201](#).

47 (d) "Physicians Licensing Board" means the board created in Section [58-67-201](#).

48 (e) "Therapeutically similar drug product" means a drug product that:

49 (i) provides the same level of therapeutic benefit and risk to a patient as another drug
50 product; and

51 (ii) is on the list of therapeutically similar drugs created by the division in accordance
52 with Subsection (9).

53 (2) A pharmacist or pharmacy intern dispensing a prescription order for a specific drug
54 by brand or proprietary name may substitute [~~a drug product equivalent for the prescribed drug~~
55 ~~only] the prescribed drug with:~~

56 (a) a therapeutically equivalent drug product if:

57 ~~[(a)]~~ (i) the purchaser specifically requests or consents to the substitution of a ~~[drug~~
58 ~~product equivalent]~~ therapeutically equivalent drug product;

59 ~~[(b)]~~ (ii) the ~~[drug product equivalent]~~ therapeutically equivalent drug product is:
60 (A) of the same generic type and is designated the therapeutic equivalent in the
61 approved drug products with therapeutic equivalence evaluations prepared by the Center for
62 Drug Evaluation and Research of the Federal Food and Drug Administration; or
63 (B) listed on the therapeutically equivalent drug list described in Subsection (9) as a
64 drug that can be substituted for the prescribed drug;

65 ~~[(c)]~~ (iii) the ~~[drug product equivalent]~~ therapeutically equivalent drug product is
66 permitted to move in interstate commerce;

67 ~~[(d)]~~ (iv) the pharmacist or pharmacy intern counsels the patient on the use and the
68 expected response to the prescribed drug, whether a substitute or not~~[-and]~~;

69 (v) the substitution is not otherwise prohibited by ~~[this chapter,]~~ law; and

70 ~~[(e)]~~ (vi) the prescribing practitioner has not indicated that a ~~[drug product equivalent]~~
71 therapeutically equivalent drug product may not be substituted for the drug, as provided in
72 Subsection (6); ~~[and]~~ or
73 ~~[(f) the substitution is not otherwise prohibited by law.]~~

74 (b) a therapeutically similar drug product if:
75 (i) the prescriber has written "therapeutically similar substitution allowed" on the
76 prescription for the prescribed drug;

77 (ii) the therapeutically similar drug product is listed on the therapeutically similar drug
78 list described in Subsection (9) as a drug that can be substituted for the prescribed drug;

79 (iii) the purchaser specifically requests or consents to the substitution of the
80 therapeutically similar drug;

81 (iv) the dispensed therapeutically similar drug product is permitted to move in
82 interstate commerce;

83 (v) the pharmacist or pharmacy intern counsels the patient on the use and the expected
84 response to the therapeutically similar drug product;

85 (vi) the substitution is not otherwise prohibited by law; and
86 (vii) the substitution;

87 (A) results in a decreased cost to the patient;

88 (B) is covered on the patient's health benefit plan formulary as a preferred drug or at
89 the same or lower payment tier;

90 (C) is necessary because the pharmacist does not have the originally prescribed
91 medication available to dispense to the patient; or

92 (D) would be beneficial to the patient for any reason if the patient and pharmacist
93 mutually agree that the substitution would benefit the patient.

94 (3) (a) Each out-of-state mail service pharmacy dispensing a [~~drug product equivalent~~]
95 therapeutically equivalent drug product or a therapeutically similar drug product as a substitute
96 for another drug into this state shall notify the patient of the substitution either by telephone or
97 in writing.

98 (b) Each out-of-state mail service pharmacy shall comply with the requirements of this
99 chapter with respect to a [~~drug product equivalent~~] therapeutically equivalent drug product or a
100 therapeutically similar drug product substituted for another drug, including labeling and record
101 keeping.

102 (4) [~~Pharmacists or pharmacy interns may not substitute without the prescriber's~~
103 ~~authorization on trade name drug product prescriptions unless the product is currently~~
104 ~~categorized in the approved drug products with therapeutic equivalence evaluations prepared~~
105 ~~by the Center for Drug Evaluation and Research of the Federal Food and Drug Administration~~
106 ~~as a drug product considered to be therapeutically equivalent to another drug product.] A
107 pharmacist or pharmacy intern that substitutes a drug for a therapeutically similar drug under
108 Subsection (2)(b), for any prescription intended to last longer than 30 days, shall notify the
109 prescriber that the pharmacist or pharmacy intern substituted the drug.~~

110 (5) A pharmacist or pharmacy intern who dispenses a prescription with a [~~drug product~~
111 ~~equivalent~~] therapeutically equivalent drug product or a therapeutically similar drug product
112 under this section assumes no greater liability than would be incurred had the pharmacist or
113 pharmacy intern dispensed the prescription with the drug product prescribed.

114 (6) (a) If, in the opinion of the prescribing practitioner, it is in the best interest of the
115 patient that a [~~drug product equivalent~~] therapeutically equivalent drug product not be
116 substituted for a prescribed drug, the practitioner may indicate a prohibition on substitution
117 either by writing "dispense as written" or signing in the appropriate space where two lines have
118 been preprinted on a prescription order and captioned "dispense as written" or "substitution

119 permitted".

120 (b) If the prescription is communicated orally by the prescribing practitioner to the
121 pharmacist or pharmacy intern, the practitioner shall indicate the prohibition on substitution
122 and that indication shall be noted in writing by the pharmacist or pharmacy intern with the
123 name of the practitioner and the words "orally by" and the initials of the pharmacist or
124 pharmacy intern written after it.

125 (7) (a) A pharmacist or pharmacy intern who substitutes a [~~drug product equivalent~~]
126 therapeutically equivalent drug product or therapeutically similar drug product for a prescribed
127 drug shall communicate the substitution to the purchaser.

128 (b) The [~~drug product equivalent~~] therapeutically equivalent drug product container or
129 therapeutically similar drug product container shall be labeled with the name of the drug
130 dispensed[~~, and the~~].

131 (c) The pharmacist, pharmacy intern, or pharmacy technician shall indicate on the file
132 copy of the prescription both the name of the prescribed drug and the name of the [~~drug~~
133 ~~product equivalent~~] therapeutically equivalent drug product or the therapeutically similar drug
134 product dispensed in [~~its~~] place of the prescribed drug.

135 (8) (a) For purposes of this Subsection (8), "substitutes" means to substitute:

- 136 (i) a generic drug for another generic drug;
137 (ii) a generic drug for a nongeneric drug;
138 (iii) a nongeneric drug for another nongeneric drug; or
139 (iv) a nongeneric drug for a generic drug.

140 (b) A prescribing practitioner who makes a finding under Subsection (6)(a) for a
141 patient with a seizure disorder shall indicate a prohibition on substitution of a [~~drug product~~
142 ~~equivalent~~] therapeutically equivalent drug product in the manner provided in Subsection (6)(a)
143 or (b).

144 (c) Except as provided in Subsection (8)(d), a pharmacist or pharmacy intern who
145 cannot dispense the prescribed drug as written, and who needs to substitute a [~~drug product~~
146 ~~equivalent~~] therapeutically equivalent drug product for the drug prescribed to the patient to
147 treat or prevent seizures shall notify the prescribing practitioner prior to the substitution.

148 (d) Notification under Subsection (8)(c) is not required if the [~~drug product equivalent~~]
149 therapeutically equivalent drug product is paid for in whole or in part by Medicaid.

150 (9) (a) [~~The division shall designate by rule made in~~] In accordance with Title 63G,
151 Chapter 3, Utah Administrative Rulemaking Act, and in consultation with the board, the
152 Physicians Licensing Board [~~created in Section 58-67-201,~~] and the Osteopathic Physician and
153 Surgeon's Licensing Board [~~created in Section 58-68-201, appropriate substitutes for~~
154 ~~albuterol.~~], the division shall create:

155 (i) a therapeutically equivalent drug product list that contains a list of drug products
156 that are therapeutically equivalent to another drug product; and

157 (ii) a therapeutically similar drug product list that contains a list of drug products that
158 are therapeutically similar to another drug product.

159 (b) [~~Subsections (2)(b) and (4) do not apply to the substitution of a drug product~~
160 ~~equivalent for albuterol.~~] The division may not add a drug product to a list described in
161 Subsection if the addition is opposed by:

162 (i) the board;

163 (ii) the Physicians Licensing Board; or

164 (iii) the Osteopathic Physician and Surgeon's Licensing Board.

165 (c) When creating a list described in Subsection (9)(a), before considering any other
166 types of drugs, the division shall consider:

167 (i) albuterol inhalers;

168 (ii) injectable forms of insulin; and

169 (iii) diabetic test strips.

170 (10) Failure of a licensed medical practitioner to specify that no substitution is
171 authorized does not constitute evidence of negligence.

172 Section 2. **Effective date.**

173 This bill takes effect on May 1, 2024.